I am Kim Wilson, Partner/Shareholder at the Raleigh law office of Lewis & Roberts PLLC. I have been a practicing attorney for 17 years; and, also recently completed my Masters in Public Health from the Department of Health, Policy & Management at UNC-Chapel Hill.

The vast majority of my career has focused on issues of health policy in one aspect or another. Additionally, I have a brother with a very successful dermatology practice in Eden, NC; a sister who has worked in the pharmaceutical industry for 20 years; two other siblings who are nurses; a sister who ran the quality assurance program for Duke University's Institutional Review Board; and, a brother in law who is the Vice President of Finance for the Medical College of Georgia. So, as you can imagine, matters of health policy are personal to me.

I appreciate the opportunity to speak with you today. My goal is to help this committee better understand what the Food & Drug Administration's role is in protecting citizens from dangerous, harmful drugs; and, this governmental entity's severe limitations in this capacity.

What is the Food & Drug Administration:

- A governmental agency with less than 10,000 employees that is responsible for promoting and protecting public health through the regulation supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

- The FDA is responsible for regulating 1 trillion dollars worth of products which constitutes 25% of all consumer spending in the US.

- The Center for Drug Evaluation and Research (commonly known as CDER) is a division of the FDA responsible for the approval of new drug applications; monitors advertising of drugs on the market by pharmaceutical companies; and, collects and analyzes safety data for drugs already on the market. **CDER is the agency responsible for drug safety.**

- CDER has approximately 1400 employees, only 72 of whom are devoted to making sure that over 3000 prescription drugs on the market are safe for over 200 million people in the US consuming prescription drugs.

The Drug Approval Process: What CDER Does and Does not Do:

- Does not test drugs for safety and efficacy.

  – CDER relies on data submitted by the drug companies for approval purposes.

- CDER receives about 50% of its budget directly from pharmaceutical companies

- Pharmaceutical companies can pay an extra fee to have drugs fast tracked for approval by CDER.

- CDER employee evaluations are tied to how many New Drug Applications are approved.

- CDER relies heavily on a pharmaceutical company to report adverse events with its drug- what is deemed an adverse event is subjective, arbitrary and subject to interpretation. This is a fact: adverse events are largely under reported and a subject of constant debate and concern within the medical community.

- During the clinical trial phase, generally a drug is only tested on 500-3000 people prior to approval by CDER; thus, the public at large is truly the "guinea pig" for all new drugs.

  - Sadly, Phase IV trials, which are post marketing trials, are seldomly ever carried out and/or enforced by CDER.

By giving the pharmaceutical industry immunity, North Carolina is saying that all the deficiencies and limitations of the FDA, specifically CDER, written about on a daily basis by physicians, researchers, employees of the FDA, former employees of the FDA and health care policy experts just do not exist. We are entrusting the health safety of our children, our parents and our spouses to the a billion dollar profitable private industry and an under funded, under staffed bureaucratic agency. Before a bill of this nature is truly considered, I urge each of you to educate yourself and your colleagues about the drug approval process and the limitations of CDER is keeping our citizens safe.

In conclusion, I want to leave you with some real experiences illustrating the short comings of the FDA which directly impacted thousands of people injured or killed by the popular arthritis drug, Vioxx. Many of those persons were citizens of North Carolina:

Vioxx, was a popular arthritis drug manufactured by Merck and launched to market in 1999. It was withdrawn from the market in 2004 because of the substantially increased risk of heart attack and strokes, even in healthy people. Revenues from Vioxx was some where between 2.5 billion and 4 billion dollars annually. I was actively involved in the Vioxx litigation for five long years. I represented many people from North Carolina who were injured or killed by the drug. Here are a few inside facts that not a lot people are aware of about the FDA, Merck & Vioxx:

Just prior to Vioxx being voluntarily withdrawn from the market by Merck, not the FDA, CDER had actually approved the use of Vioxx for children with rheumatoid arthritis- the FDA was going to permit this very dangerous, powerful pain medication to be used in our most vulnerable population that has no say in the drugs given to them by parents and physicians.

Now you may ask why Merck voluntarily withdrew its billion dollar blockbuster drug from the market? It wasn't because it feared the FDA- the FDA had just approved the drug for use in children. Merck feared the court system. Because of access to the courts, thousand of more lives were saved.

Thank you again for your time and attention today. I look forward future discussions on this very important issue.

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